UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,895	03/13/2007	Sabine Desset-Brethes	33316A	9283

1095 7590 05/19/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,895	DESSET-BRETHES ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed February 12, 2009 has been received and entered into present application. No claims were canceled or added by applicant. Thus claims 1-19 remain pending examination on the merits.

Applicants' arguments, filed February 12, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 is dependent on claim 2 but is exactly the same as claim 2 which depends on claim 1. Because it does not add any different limitations that are not already included in claim 2, it fails to further limit the claim

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant claims the outer phase “does not comprise a matrix former”’ and wherein the core is first coated with a “non functional film coat” and then with an enteric coat. The language “does not comprise a matrix former" is unclear because applicant has not defined a matrix former except to state that "hydrophilic and/or hydrophobic components can be used as matrix former” which encompasses anything. Applicant has claimed specific compounds it deems as matrix formers in claims 7-8, so those are not indefinite with regards to the matrix former, however the generic claims are unclear as to what would be considered a matrix former and thus what is not contained in the outer phase. Additionally the language of "non functional film coat" is unclear because it is not clear how a film coating on the inner core can be considered "non functional" as any coating has a function. Applicant has not definite "non functional film coat" and this does not appear to be known in the art as far as what this would comprise thus it would be unclear to one of skill in the art at the time of the invention what would be a non functional film coat.

Additionally, claims 9 and 14 contain parenthesis that are not clear if they are limitations to the claim are not. The “about 1-60 weight % (based on the total core composition)” is indefinite because it’s not clear to one of skill in the art if the 1-60 weight% is of the total composition or if "core composition" is specifically claimed.

Further, Claim 1 recites the limitation "wherein said composition comprising a core" however there is no previously mentioned composition comprising a core mentioned. Perhaps applicant meant to recite “said composition comprises a core" however this is not what is currently claimed and there is insufficient antecedent basis for this limitation in the claim.

Thus claims 1-19 are rejected for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsh et al. (US 2003/0035839 A1) in view of Tanizawa et al. (US 2004/0018235), already of record on pages 4-12 of the previous office action mailed October 08, 2009, the reasons of which are hereby incorporated by reference.

In claim 1, applicant claims a pharmaceutical composition comprising pitavastatin wherein said composition comprises a core consisting of inner phase and an outer phase, wherein the outer phase does not comprise a matrix former and wherein the core is coated with a non functional film and then with an enteric coating. Hirsh et al. teach a pharmaceutical composition that contains an outer layer and a second inner layer (abstract) and they specifically teach that it allows for oral administration in a sustained release form (page 3, [0028]). They further teach a core that can contain viscosity increasing agents such as various grades of hydroxypropyl methyl cellulose (pages 3-4, [0031]) and a outer layer of flavor particles (page 4, [0032-0034]) which would not contain a viscosity increasing agent. They further teach coating of the tablet including hydroxypropylmethylcellulose and talc (page 3, [0030]) and an enteric coating (page 6, [0061]). They do not teach pitavastatin specifically, however Tanizawa et al., already of record in the previous office action, teaches a sustained release formulation for pitavastatin (abstract) that also includes hydroxypropylmethylcellulose as component for sustained release (page 3, [0025-0027]). It would have been obvious to one of ordinary skill in the art at the time of the invention that the formulation of Hirsh et al. could be used for other active agents such as pitavastatin, especially because sustained release formulations using hydroxypropylmethylcellulose are known in the art.

There is motivation to use the formulation of Hirsh et al for pitavastatin to provide the ability to administering more than one active agent which is common in treatment of hyperlipidemia, and also because the formulation of Hirsh et al. maximizes the therapeutic effectiveness and minimizes side effects (page 1, [0006]). Thus claim 1 is unpatentable over Hirsh et al. in view of Tanizawa et al.

In claims 2-4, applicant claims about 5-50% of the composition is pitavastatin and the amount is about 1-32mg. Tanizawa et al. teaches 12mg (page 5, [0067]) which is 7% of the core product and 4% of the total tablet which would be within the "about 5-50%" and thus claims 2-4 are unpatentable over Hirsh et al. in view of Tanizawa et al.

In claims 5-8, applicant claims that the matrix former in the inner phase contains varying viscosities and also contains hydroxypropylmethylcellulose (HPMC). As discussed above, Hirsh et al. teaches various grades of viscosity of hydroxypropyl methyl cellulose (pages 3-4, [0031]) and thus claims 5-8 are unpatentable over Hirsh et al. in view of Tanizawa et al.

In claims 9-11, applicant claims that the HPMC is about 1-60% by weight and a viscosity of about 1 to about 500 cps. Hirsh et al. teaches 40-60% (page 12, [0151]) and Tanizawa et al. teaches 9.3% (table 2, [0067]) and they both teach various grades of HPMC, Tanizawa et al. specifically teaches both low and high viscosity HPMC which would have viscosities between 4000 cps (high) and 5 cps (low) and thus would be within the limits of claims 10 and 11. Thus claims 9-11 are unpatentable over Hirsh et al. in view of Tanizawa et al.

In claims 12-14, applicant claims a stabilizer and that it is magnesium aluminometasilicate at about 1-15%. Tanizawa et al. teaches magnesium alumino metasilicate at a weight of 1.3% (page 9, table 12) and it would have been obvious to add the stabilizer for pitavastatin to the composition of Hirsh et al. because the stabilizer is specific to the formulation for pitavastatin. Thus claims 12-14 are unpatentable over Hirsh et al. in view of Tanizawa et al.

In claims 15 and 17, applicant claims that the coating contains hydroxypropylmethylcellulose or talc both of which are taught by Hirsh et al. in their coating (page 3, [0030]) and they specifically teach use of an enteric coating (page 6, [0061]). Thus claims 15 and 17 are also unpatentable over Hirsh et al. in view of Tanizawa et al.

In claims 16 and 18, applicant claims a specific coating amount of 4 mg/cm2 for the non functional coat and 4 to 6 mg/cm2 for the enteric coat. Neither Hirsh et al. nor Tanizawa et al. teach these specific parameters. However it would have been obvious to one of ordinary skill in the art to look to the prior art for known methods of coating similar compositions and such a coating would be well within the limits of routine experimentation for optimal coating. Thus claims 16 and 18 are unpatentable over Hirsh et al. in view of Tanizawa et al.

In claim 19, applicant claims a method of treating hyperlipidemia with the composition of claim 1. Since pitavastatin is well known in the art to treat hyperlipidemia and taught by Tanizawa et al. (abstract) it would have been obvious' that

the formulation of Hirsh et al. with pitavastatin should be used to treat hyperlipidemia and thus claim 19 is also unpatentable over Hirsh et al. in view of Tanizawa et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Examiner, Art Unit 1614